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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/461,537	12/15/1999	JOHN C. ROYER	4216.260-US	3928
25907	7590	02/08/2005	EXAMINER	
NOVOZYMES BIOTECH, INC. 1445 DREW AVE DAVIS, CA 95616			MARVICH, MARIA	
		ART UNIT	PAPER NUMBER	
		1636		

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/461,537	ROYER ET AL.
	Examiner Maria B Marvich, PhD	Art Unit 1636

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 November 2004.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 27 and 28 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 27 and 28 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

This office action is in response to an amendment filed 11/1/04. Claims 1-26 have been cancelled. Claims 27-28 have been amended. Claims 27-28 are pending in the application.

### *Response to Amendment*

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are no new grounds of rejection herein and therefore, this action is final.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These rejections are maintained for reasons of record in the office action mailed 7/26/04 and restated below.**

Claims 27 and 28 are vague and indefinite in that the metes and bounds of "the identifying characteristics" are unclear. It is unclear how to distinguish *Fusarium venenatum* cells having "the identifying characteristics". The specification does not define "the identifying characteristics" that are to be used to identify the recited host cells nor does the prior art have a single excepted definition for "identifying characteristics". As "identifying characteristics" is a relative term, the metes and bounds of the host cell unknown.

***Response to Argument***

Applicants traverse the claim rejections under 35 U.S.C. 112, second paragraph on page 7 of the amendment filed 11/1/04. Applicants argue given the following arguments regarding the rejection of claims 27 and 28 under 35 USC 112, first paragraph, the metes and bounds of "having the identifying characteristics" are clear.

Therefore, the response to applicant's arguments are included in the response to arguments regarding the rejections under 35 USC 112, first paragraph.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **These rejections are maintained for reasons of record in the office action mailed 7/26/04 and restated below.**

Applicants recite a genus of host cells that have the identifying characteristics of *Fusarium venenatum* NRRL 30747.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to

drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

In the instant case, applicants only disclose that *Fusarium* strains are characterized physically by characteristics such as mycelium extension and cotton-like culture (see page 4, line 27-page 5, line 2). Due to the original misclassification of the host strain of the instant invention as *Fusarium graminearum*, the specific cultural characteristics recited in the specification most closely resemble *Fusarium graminearum* and not *venenatum* (page 5, line 24 through page 6, line 10). Required techniques for the proper execution of identifying *Fusarium venenatum* as well as critical primers and unique cultural details are not provided in the specification. The specification does not disclose the identifying characteristics of a non-toxic, non-toxigenic, non-pathogenic *Fusarium venenatum* NRRL 30747 host cell, which is an essential element of the claims. Neither applicant nor the prior art provide a correlation between the “characteristics” provided in the specification and *Fusarium venenatum* NRRL 30747. Given the diversity of “identifying characteristics”, and the inability to determine which will also be adequate to distinguish correct taxonomy of *Fusarium venenatum* NRRL 30747, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

***Response to Argument***

Applicants traverse the claim rejections under 35 U.S.C. 112, first paragraph on pages 4-7 of the amendment filed 11/1/04. Applicants argue that the identifying characteristics associated with strain ATCC 20334 (NRRL 30747) have not changed just the species name and therefore the characteristics recited in the specification are the identifying characteristics of ATCC 20334. Rather, the characteristics are inherent to the strain. US 3,937,654 which is referenced by the ATCC catalog in relation to ATCC 20334 discloses the morphological and growth characteristics of ATCC 20334, which characteristics are not diverse. Furthermore, the prior art has provided the required techniques for identifying other *Fusarium venenatum* strains having the morphological and growth identifying characteristics of ATCC 20334. Applicants further argue that methodologies have been and may be developed to enhance the ability to discern between different strains.

Applicants' arguments filed 11/1/04 have been fully considered but they are not persuasive. Applicants' claims are directed toward a method of producing a heterologous peptide using a host cell with the "identifying characteristics" of NRRL 30747 (ATCC 20334). However, the instant invention does not indicate what these *identifying characteristics* are. The specification disclose that *Fusarium graminearum* is characterized by various features relating to conidia, cell shape, conidophores etc (see e.g. page 5, line 24 – page 6, line 3). As regards ATCC 20334, the specification only teaches the following, that the *Fusarium* strain deposited at ATCC as 20334 has been identified as *Fusarium graminearum* Schwabe IMI 145425 and has been identified in US 4,041,189. A review of US 4,041,189 does not reveal any further

clarification as to “identifying characteristics”. Applicants appear to argue that by “identifying characteristics” is intended **all** of the growth and morphological characteristics that are disclosed for example on page 5, line 24- page 6, line 3 or alternatively disclosed in US 3,937,654. Firstly, neither the instant specification nor US 3,937,654 provide “the identifying characteristics” of ATCC 20334. Secondly, the instant disclosure provides no characteristics specific to ATCC 20334. Therefore, it is unclear what is intended by “identifying” characteristics. In other words, what characteristics are considered “identifying”. If applicants intend that by “identifying characteristics” they intend the growth and morphological characteristics outlined on (see e.g. page 5, line 24 – page 6, line 3), this is not encompassed by the instantly recited language. Rather an “identifying characteristic” can be a broad and diverse designation for which the instant specification has no disclosure.

### ***Conclusion***

Claims 27 and 28 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

February 4, 2004

  
GERRY LEFFERS  
PRIMARY EXAMINER